K081505

NOV 19 2008

510(K) Summary Preparation: **May 8th, 2008**

Manufacturer's Contact Person:

Terri Cmorey
Tel (954) 725-6493
Fax (954) 415-6059
Medica Health LTD
2842 Kelly Brooke Lane
Deerfield Beach, Florida 33442

Trade Name: Theragem Professional T1002

Classification Name, Classification Number, Class, Classification Reference:

Class. Name	Class. No	Class	21CFR
Color Therapy Mineral Lamp	ILY	II	890.5500

Regulation Name: Lamp, non-heating, for adjunctive use in pain therapy

Special Controls: There are no regulatory standards or special controls applicable for this device.

Indications For Use: The Medica Health LTD, THERAGEM PROFESSIONAL T1002 is a color therapy mineral lamp that helps to temporarily increase local blood circulation where applied, and temporarily relieve minor muscle, joint aches and pains through the use of light and color applied in a non-contact, non-heat manner. This color therapy Light device is designed for use at home, spa facilities and therapeutic centers. The Medica Health LTD, THERAGEM PROFESSIONAL T1002 provides interchangeable multi colored heads to the color therapy lamp in which there is no hazard for contacting the low ambient temperature colored heads. The color therapy multi-colored heads are secured within the lamp housing and utilizes an ergonomic stand which is designed for adjustable positioning by users in a domestic and/or professional environment. An adjustable timer control for safety functions is also incorporated into the THERAGEM PROFESSIONAL T1002. The Medica Health LTD, THERAGEM PROFESSIONAL T1002 allows the user control of the timer and intensity function thus assuming the safety level of device.

Contraindications: None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medica Health, Ltd.
% Terri Cmorey
2842 Kelly Brook Lane
Deerfield Beach, Florida 33442

NOV 19 2008

Re: K081505
Trade/Device Name: Theragem T1002
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: November 7, 2008
Received: November 10, 2008

Dear Terri Cmorey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): **K081505**

Devise Name: **Theragem T1002**

Indications For Use:

The Medica Health LTD, THERAGEM PROFESSIONAL T1002 is a lamp indicated for adjunctive use and providing temporary relief of minor muscle and joint pain. This device helps to temporarily increase local blood circulation where applied.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
And Neurological Devices

510(k) Number_____

Prescription Use __X__ or Over-the-Counter Use_____

(Optional Format 1-2-96)

Neil R Ogden for mkm

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K081505